GlaxoWellcome

March 30, 2000

9212 '00 MAR 31 A11 :19

Management Dockets,
Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1-23
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket Number: 00D-0087

Dear Sirs:

Please find enclosed GlaxoWellcome's comments on the draft Guidance for Industry – IND Meetings for Human Drugs and Biologics, Chemistry, Manufacturing, and Controls Information.

Please feel free to contact me at (919) 483-6408 if you need additional information or clarification regarding the comments.

Sincerely,

Suva B. Roy, Ph. D.
Director, Chemistry Pharmacy and Manufacturing
Regulatory Affairs and Quality Division

00D-0087

Glaxo Wellcome Inc.
Five Moore Drive
PO Box 13398
Research Triangle Park
North Carolina 27709-3398

Telephone
919 483 2100

C 1

Comments from GlaxoWellcome on the Draft Guidance for Industry -
IND Meetings for Human Drugs and Biologics
Chemistry, Manufacturing, and Controls

General Comments

We commend the Agency for recognizing that a separate IND meeting to address the Chemistry, Manufacturing and Controls (CMC) issues in drug and biologics development program are often required. We also appreciate the Agency's attempt to outline the types of information that should be submitted for a successful IND meeting for CMC issues for drugs and biologics.

Often, teleconferences and videoconferences are faster to arrange than face-to-face meetings. We suggest that the guidance also include options for requesting a teleconference or a videoconference when the agenda items are uncomplicated and amenable for remote conferencing.

Specific Comments

Lines 39 - 42 – We recommend inserting "approval" at the end of the sentence. The revised sentence to read as "The purpose of the pre-NDA or pre-BLA meetings ..... have proper content and format to facilitate Agency review for eventual *approval*."

Lines 53 - 55 – We recommend inserting "relevant" in the sentence. The revised sentence to read as "Sponsors should prepare an information package that includes a brief summary of the currently available *relevant* CMC information ..... development of the drug.

Line 66 – *1. Multidisciplinary Meeting*

In a multidisciplinary meeting adequate time should be allocated for each discipline, specifically we suggest that for CMC issues. Perhaps an acknowledgement of the need to assign time blocks during the development of the agenda would be helpful. While we recognize that one can ask for a separate CMC meeting, such a meeting may not always be needed when there are not enough issues or the issues are relatively uncomplicated.

Line 105 – We suggest replacing "can" in the sentence with "should". The revised sentence to read as "The meeting *should* also include a discussion of ..... hold issues."

Line 164 - C. Focus of Meeting

We suggest adding another bullet topic "Discussion of opportunities and benefits to presubmit the CMC section of the NDA and proposed timing."

We recognize that the topic may be premature for an EOP2 meeting, but it may be helpful in certain circumstances such as potential priority review drugs.

Line 234 - We suggest inserting "critical aspects" in item 1. Revised item 1 to read as "discuss the *critical* aspects of the drug development program."

Lines 234 - 240 - We suggest moving item 5 to item 1 and combining items 2 and 4. The revised paragraph to read as "The purpose of the pre-NDA or pre-BLA meeting is to (1) identify any major unresolved issues that can be problematic in the review and approval process, (2) identify and resolve, if possible, potential refuse-to-file issues, (3) exchange information on the proposed application that will facilitate the review process."

Line 246 - C. Focus of Meeting

We suggest adding another bullet topic "Discussion of opportunities and benefits to presubmit the CMC section of the NDA and proposed timing."

Lines 248 - 250 – We suggest inserting "approval" in the sentence. The revised sentence to read as "Typically the meeting also includes ..... hinder the review and *approval* process."

3ORNE PRESS®

:XPRESS VE

224

Jent Materials Enclosed
Cash, Cash Equivalent, or Jewelry

AIRBORNE EXPRESS.

FROM
GLAXO WELLCOME
CTRL SHIPPING DOORS 13-15
2512 S TRICENTER BLVD
DURHAM NC
USA 27713

Origin RDU

Shipment No.
2341127-972

IF DESTINATION IS OUTSIDE OF THE UNITED STATES: THESE COMMODITIES, TECHNOLOGY OR SOFTWARE WERE EXPORTED FROM THE UNITED STATES IN ACCORDANCE WITH THE EXPORT ADMINISTRATION REGULATIONS. DIVERSION CONTRARY TO U.S. LAW PROHIBITED.

2341127-972

2341127-972

Seq. No. 253

Weight 1-E
Billing Ref. 8615
Bill To

TO
USA
MD
20852

1 PC

Service

MLDA 4X